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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,849	10/22/2003	Michael V. Chobotov	1880-7 RCE	6691

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,849	CHOBOTOV ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-65* is/are pending in the application.

4a) Of the above claim(s) *34,39,47 and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-33,35-38,40-46,48-54 and 56-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 51, 52, and 63** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 51, 52, and 63 recite wherein the polyethylene glycol diacrylate (PEGDA) consists essentially of polyethylene glycol having a molecular weight between 700 and 800. It is the examiner's position that the instant specification does not support the limitation of consisting essentially of. Although paragraph [0061] of the specification teaches the PEGDA may comprise a molecular weight between 700 and 800, the specification does not teach consisting essentially of the specified molecular weight.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 31, 33, 35, 36, 44-46, 50-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al. (US 2006/0263301 A1) in view of Chobotov (US 2006/0224227 A1) and Studer (US 2005/0090901 A1).

With regard to **claims 31, 33, 35, 45, 46, 51, 53, and 54**, Vernon et al. (hereinafter Vernon) discloses a gelling material that is used to occlude abnormal vasculature in a patient's body ([0002]). The curable material comprises polyethylene glycol diacrylate (PEGDA), pentaerythritol-tetrakis(3-mercaptopropionate), and a buffer, where pentaerythritol-tetrakis(3-mercaptopropionate) clearly overlaps the instantly claimed pentaerythritol tetra 3(mercaptopropionate) ([0104]; [0086], [0088]). Vernon further teaches wherein the gelling material is introduced in the abnormal vasculature via a catheter syringe, which clearly overlaps the instantly claimed delivery device ([0091]; [0102]). This catheter syringe is clearly capable of accessing perigraft space between an endovascular graft and a lumen wall. Vernon further teaches wherein the catheter comprises a balloon that occludes the vasculature to reduce blood flow through the abnormal vasculature ([0095]).

Vernon teaches wherein the gelling material is utilized to occlude an abnormal vasculature, specifically any known embolization technique ([0107]). An aneurysm is a common abnormal vasculature that is occluded with a stent graft, as is well known in the art. However, Vernon does not specifically disclose a stent-graft that comprises an inflatable graft.

Chobotov discloses a stent-graft utilized to treat an aneurysm ([0002]). As shown in Figures 1 and 10, the graft comprises proximal and distal cuffs (64 and 65) and an inflatable channel (93) ([0040]; [0047]). Since Chobotov discloses a well-known stent-graft that treats an abnormal vasculature, it would have been obvious at the time of the invention for Vernon to utilize the stent-graft of Chobotov.

Vernon in view of Chobotov would therefore produce a system for deploying a gelling material into the abnormal vasculature, an aneurysm, which is also occluded with the stent-graft of Chobotov. Therefore, the gelling material would be delivered in the perigraft space between the stent-graft and a vessel lumen wall.

The PEGDA of Vernon comprises a molecular weight of 570 ([0086]). However, it is well known in the art to utilize PEGDA with higher molecular weights, absent evidence to the contrary. Studer discloses a PEGDA with a molecular weight of 700 to occlude an intervetebral space ([0042]). Therefore, it would have been obvious to one of ordinary skill in the art for Vernon to utilize PEGDA with a higher molecular weight, specifically 700.

With regard to **claim 36**, Vernon further discloses adding a radiopaque agent to the gelling material ([0087]).

With regard to **claim 44**, since the gelling material is disclosed as curing once in the patient's body to form a gelled composition, the material intrinsically comprises a first viscosity upon delivery to the perigraft space ([0104]). The material then is solid once the material has cured into the gelled composition.

With regard to **claim 50**, the polyethylene glcycol is utilized in Example 3 of Vernon at 52 wt% (997mg/1894mg), which clearly overlaps the instant claim ([0116]).

With regard to **claim 52**, the pentaerythritol-tetrakis(3-mercaptopriopionate) is in a proportion 0.43 times the weight percent of the polyethylene glycol diacrylate in Example 3 of Vernon.

6. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al. (US 2006/0263301 A1) in view of Chobotov (US 2006/0224227 A1) and Studer (US 2005/0090901 A1) as applied to claim 31 above, and further in view of Stack et al. (US 5,059,211).

Vernon in view of Chobotov and Studer disclose a system for deploying a gelling material to an abnormal vasculature. An occlusion balloon, delivered on a catheter, is utilized to reduce blood flow through the abnormal vasculature. Although Vernon in view of Chobotov and Studer does not specifically disclose the catheter as comprising a guidewire, it is well known in the art for guidewires to aid in the delivery of a catheter through a patient's vasculature. Stack et al. (hereinafter Stack) teaches a catheter guided with the aid of guidewire (column 3, lines 36-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the catheter of

Vernon in view of Chobotov and Studer to comprise a guidewire so that the occlusion balloon is positioned adjacent the distal end of the guidewire.

7. **Claims 37, 38, 40-43, 48, 49, and 56-65** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al. (US 2006/0263301 A1) in view of Chobotov (US 2006/0224227 A1) and Studer (US 2005/0090901 A1) as applied to claim 31 above, and further in view of Argentine (US 2005/0052946 A1).

With regard to **claims 37, 38, 41, 48, and 49** Vernon in view of Chobotov and Studer disclose a system for deploying a gelling material to an abnormal vasculature. The gelling material comprises a buffer such as saline utilized in an amount of 25 wt% (473mg/1894mg) of the total gelling composition ([0088]; Example 3, [0116] of Vernon). However, Vernon in view of Chobotov and Studer does not specifically disclose the buffer as glycylglycine.

Argentine teaches that glycylglycine buffer is a common alternative to saline buffer ([0084]). Additionally, Argentine discloses a curable material that comprises glycylglycine buffer from 22-27 wt% ([0076]; [0077]). Since Argentine teaches that it is known in the art to utilize the buffer glycylglycine in a curable material used in a patient's vessel ([0076]), it would have been obvious at the time of the invention for Vernon in view of Chobotov and Studer to also utilize glycylglycine buffer in the amount disclosed by both Vernon and Argentine.

With regard to **claim 40**, the polyethylene glcycol is utilized in Example 3 of Vernon at 52 wt% (997mg/1894mg), which clearly overlaps the instant claim ([0116]).

With regard to **claims 42 and 56-63**, the pentaerythritol-tetrakis(3-mercaptopriopionate) is in a proportion 0.43 times the weight percent of the polyethylene glycol diacrylate in Example 3 of Vernon.

With regard to **claims 43 and 64**, Vernon further discloses bases and surfactants in the gelling composition that clearly overlap the instantly claimed inert biocompatible materials.

With regard to **claim 65**, since the gelling material is disclosed as curing once in the patient's body to form a gelled composition, the material intrinsically comprises a first viscosity upon delivery to the perigraft space ([0104]). The material then is solid once the material has cured into the gelled composition.

Response to Arguments

8. Applicant's arguments, filed 02/26/2008, with respect to Chobotov (US 7,147,661), Leschinsky (US 2001/0029349 A1), Hubbell (US 6,958,212) have been fully considered and are persuasive. The rejections have been withdrawn.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

06/19/2008
/Amy T Lang/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731